KpnI at about coordinate 3500 of plasmid λ-J19 [is the expression product of a host transformed with a vector containing a nucleic acid fragment of plasmid λ-J19, and wherein said nucleic acid fragment extends from the restriction site PstI at about coordinate 800 to the restriction site KpnI at about coordinate 3500 of plasmid λ-J19],

G2 cont

(b) raising antibodies against said antigen, and

(c) recovering said antibodies.

REMARKS

Support for this amendment is found throughout the specification and particularly, at page 4, line 3 through page 5, line 9, and page 9, lines 32-36. Accordingly, this amendment does not add new matter and entry is respectfully requested.

The specification is objected to and claims 23, 32, and 33 are rejected under 35 U.S.C. § 112, first paragraph, as the specification allegedly does not describe the claimed subject matter in such a way as to reasonably convey to one skilled in the art that the inventors, at the time the application was filed, had possession of the claimed invention.

The Examiner indicates that the basis for this rejection is that the specification does not provide "demonstrative evidence that applicants were in possession of the claimed HIV-1 antigens (i.e., the Gag, Pol, and Env proteins purportedly encoded by the λ-J19 inserts) and that methods for the production and recovery of HIV-1 specific antibodies were adequately described." (Paper No. 18 at 1.) Applicants respectfully traverse the rejection.

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The function of the written description requirement under the first paragraph of 35 U.S.C. § 112 is to clearly convey the subject matter that an applicant has invented as of the filing date of the application relied on. *In re Barker*, 559 F.2d 588, 592 n.4, 194 U.S.P.Q. 470, 473 n.4 (C.C.P.A. 1977), *cert. denied*, 434 U.S. 1064 (1978). The applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he was in possession of the invention, i.e., whatever is now claimed. *Vas-Cath Inc. v. Mahurkar*, 19 U.S.P.Q.2d 1111, 1117 (Fed. Cir. 1991). Applicants submit that the specification clearly provides an adequate written description, which conveys to those skilled in the art, that applicants were in possession of the claimed invention.

The claims are drawn to a method of producing antibodies to an antigen of HIV-1 comprising providing an antigen, which corresponds to the recited restriction site of λ-J19, raising antibodies against the antigen, and recovering the antibodies. The claims no longer recite that the particular antigen is an "expression product of a host."

Staehelin v. Secher, 24 U.S.P.Q.2d 1513, (Bd. Pat. App. & Int. 1992) states that the inquiry for determining whether or not the specification complies with the written description requirement is whether:

> One following applicant's specification would necessarily select the later claimed subject matter. *Freerksen v. Gass*, 21 U.S.P.Q.2d 2007 (B.P.A.I. 1990). The question, therefore, is whether the originally filed application would have conveyed to a person of ordinary skill in the art that applicants invented the subject matter later claimed by them including the limitations in question. *In re Smyther*, 480 F.2d 1376, 178 U.S.P.Q. 279 (C.C.P.A. 1973).

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Applicants' specification provides a sufficient disclosure to adequately support the claimed invention. For example, applicants teach that the antigens of the claimed invention are useful as immunogens and vaccine compositions. (Specification at 14, line 1-4 and 9-12.) The antigens of the claimed invention are further described at page 4, line 30 through page 5, line 9. Therein applicants specifically teach the antigens recited in the claims, i.e., the restriction site from KpnI at about coordinate 6100 to BglII at about coordinate 9150; from KpnI at about coordinate 3500 to BglII at about coordinate 6500; and Pst at about coordinate 800 to KpnI at about coordinate 3500. Of course, one having skill in the art would immediately appreciate that the production of antibodies necessarily flows from the use of an antigen in a vaccinating or immunogenic composition.

This is supported by Hurn and Chantler, which describe well-known methods of producing reagent antibodies by immunization of a host animal with an immunogen. The resulting antibodies are further purified by known methods. In addition, Berzofsky et al. discuss antigen-antibody interactions. More particularly, Berzofsky et al. teach that "antibodies can be raised, by design of the investigator, with specificity for almost any substance known." (Berzofsky et al. at 316, lines 2-4.) Therefore, these references attest to the skill in the art at the time the claimed invention was made to raise antibodies against a particular antigen.

In view of the foregoing amendments and remarks, applicants respectfully request withdrawal of the instant rejection.

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Claim 23 is rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Putney et al.. Applicants respectfully traverse the rejection.

As noted in the Response to Paper No. 16, filed May 22, 1996, applicants claim the benefit of their prior application Serial No. 06/771,230, filed on August 30, 1986. This prior application provides an adequate written description and an enabling disclosure of the claims. Putney et al., on the other hand, was published December 12, 1986, well after applicants' priority date. Accordingly, this reference is improperly applied as "prior art" under 35 U.S.C. § 102(b) and withdrawal of the rejection is respectfully requested.

Claims 23, 32, and 33 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Luciw and Dina. Applicants respectfully traverse the rejection.

The Luciw and Dina patent was issued on October 20, 1992. However, as noted above, this application retains the benefit of S.N. 06/771,230, filed on August 30, 1986, which is well before the issue date of the Luciw and Dina patent. Moreover, it is noted that the '230 application provides an adequate written description and enabling disclosure of the claimed invention. Accordingly, this reference is improperly applied as "prior art" against the instant application and withdrawal of the rejection is respectfully requested.

Applicants respectfully request that this Amendment under 37 C.F.R. § 1.116 be entered by the Examiner since the proposed amendments do not raise new issues or necessitate the undertaking of any additional search of the art by the Examiner. In addition, Applicants request

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the Examiner's reconsideration and reexamination of the application, and the timely allowance of the pending claims.

In the event the Examiner diagrees, he is invited to call the undersigned to discuss the remaining issues.

If there are any other fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 06-0916. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted,

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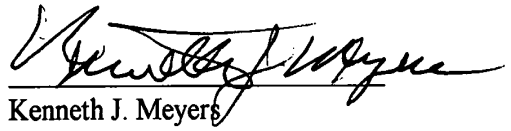
By: 
Kenneth J. Meyers
Reg. No. 25,146

Dated: December 18, 1996

Enclosures: (1) Hurn and Chantler
(2) Berzofsky et al.

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